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Protocol for a prospective observational study to improve pre-hospital notification of injured patients presenting to trauma centres in India

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Complete List of Authors:	Mitra, Biswadev; Monash University, Gupta, Amit; All India Institute of Medical Sciences, Surgery Cameron, Peter; Monash University, Department of Epidemiology and Preventive Medicine O'Reilly, Gerard; Monash University, Emergency medicine Soni, Kapil; All India Institute of Medical Sciences, Surgery Kaushik, Gaurav; All India Institute of Medical Sciences, Surgery Howard, Teresa; The Alfred Hospital, National Trauma Research Institute Fahey, Madonna; Monash University, National Trauma Research Institute Stephenson, Michael; Ambulance Victoria Kumar, Vineet; Lokmanya Tilak Municipal Medical College and General Hospital, Surgery Vyas, Sharad; BJ Medical College Dharap, Satish; Lokmanya Tilak Municipal Medical College and General Hospital, Surgery Patel, Pankaj; Smt NHL Municipal Medical College, Orthopaedic Surgery Thakor, Advait; Smt NHL Municipal Medical College Sharma, Naveen; All India Institute of Medical Sciences, Surgery Walker, Tony; Ambulance Victoria Misra, Mahesh; All India Institute of Medical Sciences, Surgery Gruen, Russell; Nanyang Technological University Fitzgerald, Mark; The Alfred Hospital, National Trauma Research Institute Mathew, Joseph; The Alfred Hospital, National Trauma Research Institute
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Biswadev Mitra, MBBS, MHSM, PhD, FACEM

Amit Gupta, MBBS, FSIM, FCLS, FACS

Prof Peter A. Cameron, MBBS, MD, FACEM

Gerard O'Reilly, MBBS, MPH, MBiostat, PhD, AStat, FACEM

Kapil Dev Soni, MBBS, MD

Gaurav Kaushik, MSc, PhD

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Mick Stephenson, ASM, B Hlth Sci, Grad Dip Hlth Sci (MICA), RN

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On behalf of the Australia-India Trauma System Collaboration

Correspondence:

Biswadev Mitra

89 Commercial Road, Melbourne, Victoria 3004

P: +61 39076 2782

F: +61 39076 2699

E: biswadev.mitra@monash.edu

ABSTRACT

Introduction: Pre-hospital notification of injured patients enables prompt and timely care in hospital through adequate preparation of trauma teams, space, equipment and consumables necessary for resuscitation, and may improve outcomes. In India, anecdotal reports suggest that prehospital notification, in those few places where it occurs, is unstructured and not linked to a well-defined hospital response. The aim of this manuscript is to describe, in detail, a study protocol for the evaluation of a formalised approach to prehospital notification.

Methods and Analysis: This is a longitudinal prospective cohort study of injured patients being transported by ambulance to major trauma centres in India. In the pre-intervention phase, prospective data on patients will be collected on pre-hospital assessment, notification, in-hospital assessment, management and outcomes and recorded in a new tailored multi-hospital trauma registry. All injured patients arriving by ambulance and allocated to a red or yellow priority category will be eligible for inclusion. The intervention will be a pre-hospital notification application to be used by ambulance clinicians to notify emergency departments of the impending arrival of a patient. The proportion of eligible patients arriving to hospital after notification will be the primary outcome measure. Secondary outcomes evaluated will be availability of a trauma cubicle, presence of a trauma team on patient arrival, time to first chest x-ray and in-hospital mortality.

Progress: Ethical approval has been obtained from the All India Institute of Medical Sciences, New Delhi and site-specific approval granted by relevant trauma services. Results will be fed back to pre-hospital and hospital clinicians via a series of reports and presentations. These will be used to facilitate discussions about service redesign and implementation. It is expected that evidence for improved outcomes will enable widespread adoption of this intervention among centres in all settings with less established tools for pre-hospital assessment and notification.

Strengths and limitations of this study

Strengths:

- This study attempts to address the burden of trauma in a setting with high incidence of injuries and high mortality rates.
- Most deaths occur pre-hospital and interventions in this setting has the potential to deliver the greatest benefit
- This is the first study on implementation and evaluation of a structured pre-hospital notification system in India

- Associations of the intervention to tangible outcomes of hospital mortality will further define the value of such intervention

Limitations:

- This study includes only four major trauma centres in India, and thus will capture only a small proportion of the population at risk
- Outcomes are limited to analysis in-hospital and further studies will be requires to assess longer term functional outcomes of injured patients

BACKGROUND

There is now growing evidence that providing trauma care within a well-organized system saves many lives and prevents long-term disability.[1-3] The basis of a well-organized trauma system is an agreed trauma triage process at each step along the patient journey. The correct level of pre-hospital response is based on specified criteria. This is then followed by transfer to an appropriate facility based on patient, mechanistic, and geographic data. The hospital response on patient arrival is based on this pre-hospital data with additional information about pre-hospital treatment and response to early treatment.

In major trauma resuscitation, management of immediately life-threatening injuries requires rapid identification and management of threats to airway, breathing, circulation and brain function. With sufficient notice, trauma hospitals can usually mobilise a team with relevant expertise, which may involve an anaesthetist, surgeon and emergency physician, specialist nurses and a radiographer, to be present and ready for patient arrival. Pre-hospital notification alone has been found to be independently associated with reduced mortality in trauma centres.[4] Some notification is common in highly developed trauma systems, usually by radio to the triage desk of the receiving hospital, although standards have not been set for the format or content of communicated information.

In India, patients are brought to hospital by various means, e.g. in Delhi 42% of the 9021 seriously injured were transported by Delhi Police, whereas only 2% were transported by ambulance in 2014 (unpublished reports). Pre-hospital notification is rare but is theoretically possible because ambulance and police usually carry Very High-Frequency (VHF) radio units. Most pre-hospital and hospital staff carry personal mobile phones that may also be used for communication. In addition to expediting specialist care on arrival to hospital, pre-hospital communication also enables information sharing from the trauma centre to the caller (such as “ensure the airway is clear” or “if you can see the bleeding site, apply pressure”), which may be valuable for variably trained non-medical transporters.

The aims of this project were to evaluate current pre-hospital assessment and notification practice and assess the effectiveness of a protocolised pre-hospital notification system using existent smartphones to improve the rate of pre-hospital notification of injured patients arriving to major trauma centres. Secondary aims were to assess the effect of this intervention on the availability of an appropriate trauma cubicle on patient arrival, the formation of an appropriate receiving trauma team, time to first radiological imaging and in-hospital mortality.

Setting: The study will be conducted in four major trauma centres in India. The Jai Prakash Narayan Apex Trauma Center, All India Institute of Medical Sciences (AIIMS), New Delhi admits approximately 4000 injured patients per year. Guru Tegh Bahadur (GTB) Hospital is a 1,500-bed hospital situated in the National Capital Region of Delhi, India, with a trauma census of approx. 1500 per year. The Lokmanya Tilak Municipal General (LTMG) Hospital is a Level I trauma centre, which caters to the megapolis of Mumbai and receives about 2500 patients with limb or life threatening injuries per year. The Sheth Vadilal Sarabhai General (VS) Hospital caters to areas in and around Ahmedabad with an average annual admission secondary to trauma of about 1200/year.

Study design: This is a prospective cohort study of injured patients being transported by ambulance to the major trauma centre study sites. The study will employ the Plan-Do-Study-Act cycles of implementation and evaluation.[5] This model will be adapted for this project into three phases: Assessment of current practice (observation of current practice and data collection), intervention (reporting of research findings directly to service providers and introduction of the pre-hospital notification through smartphones) and evaluation (of service change through further observation and data collection).

Study population/recruitment procedure: All injured patients arriving by ambulance and allocated to a red (1^{st}) or yellow (2^{nd}) priority category will be eligible for inclusion. Data will be collected prospectively by trained data collectors positioned in the trauma centres. Pre-hospital data will be abstracted by data collectors from ambulance worksheets at the time of patient arrival. All data will be entered into a trauma registry and patients will be followed up to hospital discharge. A flow chart of the study population is illustrated in Figure 1.

Retrospective inclusion in the registry will be continued for all screened patients presenting to any of the included hospitals with injury (including near-drowning) as the primary diagnosis and with at least one of the following criteria:

1. Admission to hospital
2. Death after triage but before admission
3. Dead on arrival

Exclusion criteria: Patients meeting screening criteria will be subsequently excluded from the registry if they meet any of the following criteria:

1. Dead at scene
2. Alive at triage but not admitted to hospital (discharged alive without hospital admission)
3. Isolated poisoning
4. Isolated burns
5. Single digit finger or toe amputations (unless of the thumb or great toe), only

Intervention: The pre-hospital notification application is an android application that will be used by ambulance and emergency clinicians in India to notify emergency departments of selected hospitals of an impending arrival of a patient requiring advanced lifesaving assistance. Pre-hospital clinicians will receive training on use of this application which will be accessible from personal smartphones. The application will use a simple algorithm based on trauma triage principles developed by the Australia India Trauma Systems Collaboration (AITSC).

The pre-hospital notification application will be able to collect basic patient identifiers and using an algorithm designed by the AITSC, push derived information to designated receivers. The pre-hospital triage process for injured patients was collaboratively developed using a combination of the current AIIMS trauma flag system (Figure 2), the Field Triage Decision Scheme developed by the American College of Surgeons and guidelines for trauma triage at The Alfred Hospital Emergency & Trauma Centre, Victoria, Australia.[3 6] Data points were determined after taking into account the variation in training among pre-hospital clinicians in the study setting, avoiding criteria that require a high level of clinical judgment. The final algorithm is presented in Table 1 and on the basis of selected criteria, classifies patients to three priorities for trauma resuscitation:

Priority 1 (Red): Serious life threatening injury/illness
Victims with life-threatening injuries or illness (such as head injuries, severe burns, severe bleeding, cardiac arrest, breathing-impaired, internal injuries) are assigned a priority 1 or "Red" Triage tag code (meaning first priority for treatment).
Priority 2 (Yellow): Moderate to serious injury/illness (not immediately life-threatening).

Victims with potentially serious (but not immediately life-threatening) injuries (such as fractures) are assigned a priority 2 or "Yellow" (meaning second priority for treatment) Triage tag code.

Priority 3 (Green): "Walking-wounded" Victims who are not seriously injured
Triaged as "walking wounded", and a priority 3 or "green" classification (meaning delayed treatment).

Funding: This project is part of the Australia-India Trauma Systems Collaboration (AITSC) that brings together public and private sector clinicians and researchers to improve information, resources and pilot new systems of care. Commencing in 2013, the Australian and Indian Governments invested through their Australia-India Strategic Research Fund Grand Challenge Scheme, to find the best ways of delivering needed care to injured people. The AITSC is funded through the former Grand Challenge Fund. Australia's Department of Industry, Innovation, and Science (DIIS) and the Government of India's Department of Science and Technology (DST) jointly manage the Grand Challenge Fund. It is expected that these projects will lay the foundations for a national trauma system in India, and improved trauma care in much of Australia. They will also provide needed evidence about low-cost trauma system interventions that could be implemented in most countries without the need for major health system redesign.

The protocol is registered at clinicaltrial.gov, ID No: NCT02877342.

RESULTS

Demographics: Patient demographics will be collected to define the population and ensure selection of a representative sample. Data collected will include data and time of presentation, age, sex, place of residence.

Potential confounders: Data on potential confounders, i.e. variables associated with utilisation of the pre-hospital notification tool and pre-hospital notification will be collected and presented in Table 1. Pre-hospital variables will include vital signs- systolic blood pressure (in mm Hg), pulse rate (in beats/min), respiratory rate (in breaths/min), and consciousness on the alert, voice, pain, responsive (AVPU) scale. Mechanism and place of injury details will also be collected. The pre-hospital trauma priority flag (red, yellow or green) will be collected if generated by the intervention or communicated by pre-hospital staff.

Data on potential demographic and injury characteristic confounders to secondary outcomes will be collected and include designation of person receiving notification, mechanism and intent of injury, transport type. Data on potential clinical confounders include in-hospital vital signs- systolic blood pressure, heart rate, respiratory rate and GCS with additional data on GCS components and oxygen saturation. Management data collected will include emergency department disposition times, details on in-hospital operative procedures, in-hospital radiological investigations, neurosurgical consultation, and blood transfusions. Further details on injury severity will be collected using the Abbreviated Injury Severity (AIS) scale codes.

Primary Outcome: Pre-hospital notification will be the primary outcome, defined as a phone call or message to a treating hospital clinician regarding an injured patient enroute to hospital. For the purpose of this research project, a patient will satisfy primary outcome criteria if pre-hospital notification with any information has occurred. This variable will be collected and analysed as a binary variable.

Secondary outcomes: A trauma call-out will be recorded as a binary variable- whether one has occurred or not. Date and time of this callout will also be recorded.

The presence of a trauma team leader at the time of patient arrival will be collected as a binary variable. This is the person whose role is to co-ordinate the trauma resuscitation (primary and secondary survey) - this is, generally, a hands-off role undertaken by the most senior clinician in the trauma team. The team leader should be someone not already/always present in the area where trauma bay is located; and have the ability to lead or make decisions regarding treatment (e.g. emergency transfer to operating theatre or not). The leader is expected to be present by the time of patient arrival at the definitive care hospital. The designation of the usual team leader is site specific:
JPN: Senior Resident
GTBH: Senior Resident
VSH: Third year Resident
LTMGH: Third year surgical resident

Readiness of a trauma bay is defined as at least 1 trauma bay that has been allocated and empty (therefore ready to receive a patient) on arrival. Time at which the first chest x-ray commenced will be recorded. The location to which a patient was discharged on completion of hospital management will be recorded and the secondary outcome for in-hospital death collected as a binary variable.

Pre-defined subgroup analyses will be conducted on each centre, severity of injury on presentation, i.e. “red” and “yellow” category and patients who are declared dead on arrival.

Data analysis: Continuous data will be summarised using mean with standard deviation if normally or near-normally distributed or with medians and inter-quartile ranges for skewed data. Ordinal data will be summarised using medians and inter-quartile ranges. Nominal, including binary, data will be presented as counts with proportions within their categories. Statistical significance will be defined as $p<0.05$. A difference between means will be analysed for statistical significance using the Student’s t-test while the Wilcoxon Rank Sum test will be used for assessing statistical significance for a difference between medians. The chi-squared test or Fisher’s exact test will be used for nominal data according to cell frequencies. All analyses will be performed using Stata v 12.0 (Statacorp, College Station, Texas, USA).

Sample size: The proportion of patients achieving the primary outcome after intervention was targeted to be 0.70 (achieved by consensus among trauma leaders in Australia and India). This was considered to be a clinically significant level compared to anecdotal reports of current practice at extremely low rates of pre-hospital notification.

The minimum acceptable difference from this hypothesized ideal proportion was considered to be 10%, with a one-sided absolute difference of >10% (i.e. less than 0.6) to be considered as failure to achieve the primary outcome. The estimated sample size for a one-sample comparison of proportion with the hypothesized value of 0.70, an alpha of 0.05 and power of 0.90 was 191 after intervention.

Ethics and dissemination: Although this study primarily involves service evaluation, ethical approval was obtained to allow collection of patient identifiers. Therefore, full ethical approval has been obtained from the All India Institute of Medical Sciences (AIIMS), New Delhi, India, and site-specific approval has been acquired from the relevant trauma services. Registration of this research has also been submitted to Monash University Human Research Ethics Committee (MUHREC) and is awaiting final approval. Study results will be disseminated among pre-hospital and hospital clinicians across participating sites. It is expected ongoing evaluation will inform sustainability of the proposal and requirements for refreshers. It is expected that study findings will be presented at scientific congresses and published in peer-reviewed manuscripts.

DISCUSSION

Currently, injury in India is a leading cause of years of productive life lost and the leading cause of death for those under 35 years old. This national injury burden is growing and the ongoing rise in the trauma burden is mostly in the form of road traffic crashes. India has 1% of the total vehicles in the world yet accounts for 6% of total road accidents globally. It is estimated that there are 400,000 road traffic crashes in India each year, resulting in 100,000 deaths and 1.2 million individuals who are seriously injured.

International establishment of trauma systems incorporating centralised trauma centres has helped address the injury burden by providing prompt, specialist trauma care. In such systems, effective therapy for the severely injured is facilitated by an interdisciplinary and integrated (horizontal) approach to undifferentiated trauma with input from pre-hospital and in-hospital resuscitation teams.[7]

Smartphones currently include all the features of a laptop, including web browsing, Wi-Fi, and third-party application. Currently the most popular smartphones are Google's Android, Apple's IOS mobile operating systems and Nokia-X series. As well as being technologically advanced, India’s adoption of smartphones and tablets has been high and continues to rapidly grow. Doctors in emergency departments have smartphones and ambulance services have access to smartphones and/or tablets in their ambulances. Similar technology has been successfully used to monitor patients with chronic health needs and self-examination.[8] There is currently no standardised system of pre-hospital notification in India for injured patients. The public ambulance system in India is rapidly expanding, adopting computerised systems of GPS tracking and call allocation similar to high-income countries.

This will be the first study to assess utilisation of a smartphone-based intervention to improve pre-hospital notification. The overarching aim of this project will be to test whether lives are saved by new approaches to communication between pre-hospital care providers (ambulance, emergency, and police services) and receiving hospitals, before the patient arrives. Standardised, locally tailored protocols will be used for notifying and responding to a seriously injured person who is being brought to hospital.

Previous studies evaluating trauma outcomes in India have been limited with absence of pre-hospital data and inability to evaluate the influence of pre-hospital factors on trauma outcomes.[9] This intervention and the accompanying registry will be among the first to include robust pre-hospital data, collected prospectively, in evaluating trauma outcomes. Trauma registries are integral to trauma system improvement. In developing countries, where the burden of injury is much greater, the known activity of trauma registries is much less.[10]

This project is fully funded and has progressed to development of the smartphone application and training of data collectors. Relevant ethics committee approvals as described above have been obtained. Pre-intervention data collection is expected to commence in May 2016.

CONCLUSIONS

Routine pre-hospital notification of injured patients to the receiving trauma centre is currently not practiced in India. This study will prospectively record the current practice of pre-hospital notification, management across pre-hospital and hospital phases and outcomes of injured patients presenting to four major trauma centres in India. We aim to develop a smartphone application, incorporating essential information for accurate triage of injured patients. The effect of this intervention on pre-hospital notification rates, along with overall trauma processes and outcomes will be evaluated in a prospective observational study. It is expected that successful evaluation will enable widespread adoption of this intervention in India and other countries.

CONTRIBUTORSHIP Statement

The project was planned by RG, MF, MM, AM and AT. Study design was unbdertaken, in consultation with all authors, by BM, PC, TH, MF, VK and JM. Site-specific processes were arranged and processes unique to each site added to the manuscript by KS, GK, SD and PP. Biostatistician GO reviewed the proposal and provided input to research design and analysis. MS and TW provided expert opinion on pre-hospital systems. All authors reviewed and edited the final manuscript.

Conflicts of Interest

None to declare

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Figure 1. Patient recruitment Flow Diagram

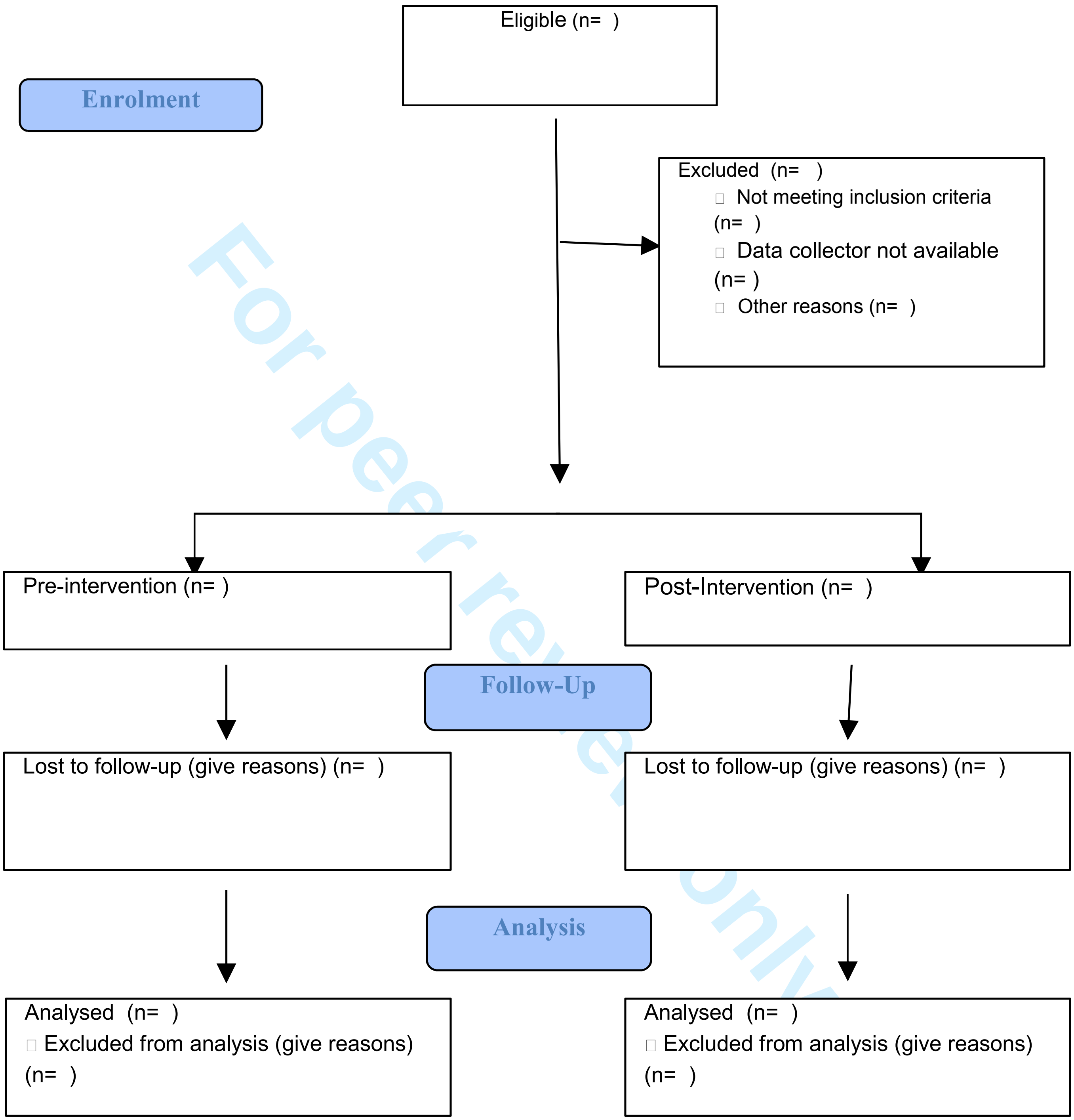
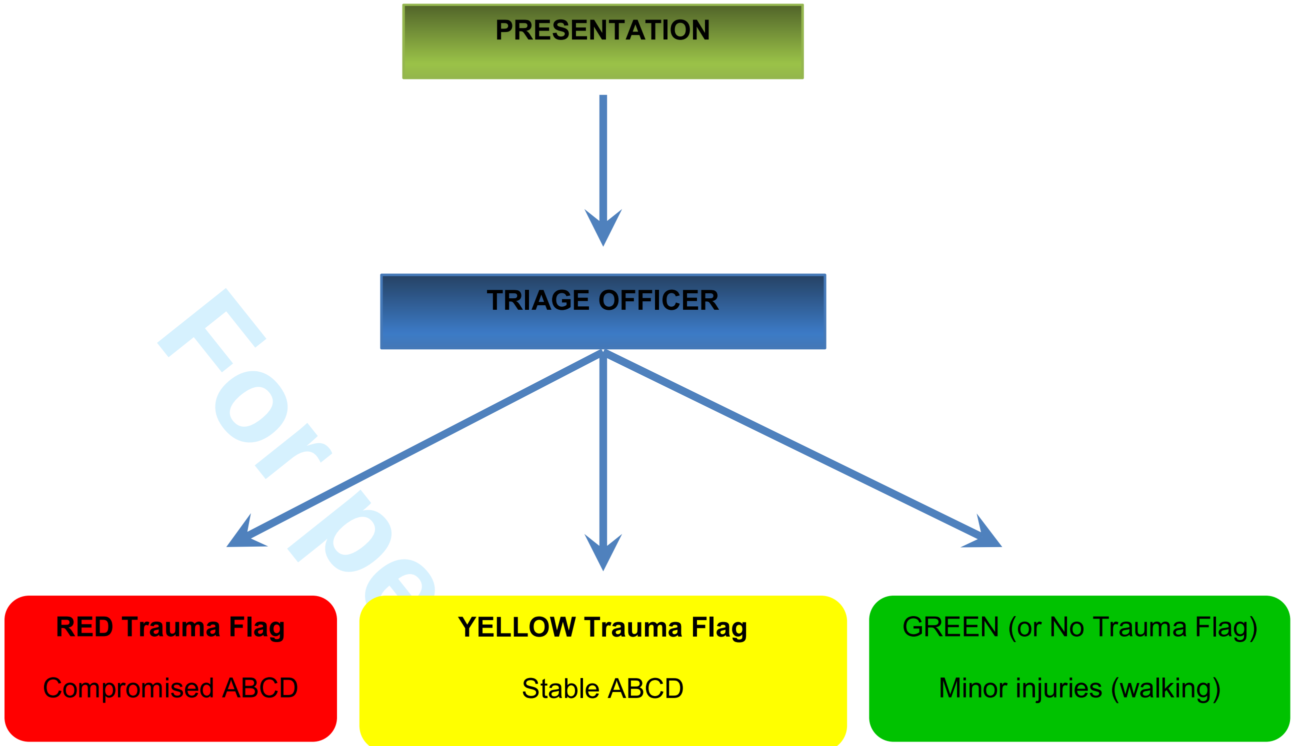


Figure 2. Trauma triage protocol



ABCD: Airway, Breathing, Circulation, Disability

Table 1. Pre-hospital data collection using smartphone application and generation of trauma priority flag

Demographics	Age - Years Sex
Mechanism of injury	RTI - (Road traffic incident) High Speed RTI pedestrian / bicycle RTI motorbike RTI unspecified Fall from height (10 feet/3 metres)[a] Penetrating trauma- Stab / Gunshot[a] Railway incident[a] Blunt Assault Near drowning[a] Other
Serious Injury Identification	Penetrating to head, neck, torso[a] Chest injury including pneumothorax[a] Crush injury including degloving[b] Amputation proximal to wrist and ankle[a] Suspected pelvic injury[b] Open or closed suspected skull fracture[a] Spinal Injury[a] Other
Vital Signs	Systolic Blood Pressure - Record actual value in mmHg - < 90[a] - ≥90 Heart Rate - Record actual value – heart rate per minute - ≥120[b] - <120 Respiratory Rate - Record actual value – respirations per minute - <12 beats per minute[b] - >24 beats per minute[b] - Normal – 12 – 24 AVPU - Alert - Verbal[a] - Responding to Pain[a] - Unconscious[a]

AUTOMATIC FLAG-GENERATION RULES

[a] Presence of a variable generates a RED flag
[b] Presence of two or more variables generates a RED flag
[b] Presence of one variable only generates a YELLOW flag
Presence of none of the numbered variables generates a GREEN flag

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Correspondence:

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- Association of the intervention to hospital mortality will further define the value of such intervention

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In India, patients are brought to hospital by various means, e.g. in Delhi 42% of the 9021 seriously injured were transported by Delhi Police, whereas only 2% were transported by ambulance in 2014.[5] Pre-hospital notification is rare but is theoretically possible because ambulance and police usually carry Very High-Frequency (VHF) radio units. Most pre-hospital and hospital staff carry personal mobile phones that may also be used for communication. In addition to expediting specialist care on arrival to hospital, pre-hospital communication also enables information sharing from the trauma centre to the caller (such as “ensure the airway is clear” or “if you can see the bleeding site, apply pressure”), which may be valuable for variably trained non-medical transporters.

The primary aim of this project is to evaluate the effectiveness of a protocolised pre-hospital notification system using existing smartphones to improve the rate of pre-hospital notification of injured patients arriving to major trauma centres. Secondary aims were to assess the effect of this intervention on the availability of an appropriate trauma cubicle on patient arrival, the formation of an appropriate receiving trauma team, time to first radiological imaging and in-hospital mortality.

METHODS

Setting: The study will be conducted in four major trauma centres in India. In India, any teaching hospital serviced by specialty departments of general surgery, orthopaedics and neurosurgery are considered to be major trauma centres. The Jai Prakash Narayan Apex Trauma Center, All India Institute of Medical Sciences (AIIMS), New Delhi admits approximately 4000 severely injured (ISS>12) patients per year. Guru Tegh Bahadur (GTB) Hospital is a 1,500-bed hospital situated in the National Capital Region of Delhi, India, with a trauma census of approx. 1500 patients per year with limb or life threatening injuries. The Lokmanya Tilak Municipal General (LTMG) Hospital is a Level I trauma centre, which caters to the megapolis of Mumbai and receives about 2500 patients with limb or life threatening injuries per year. The Sheth Vadilal Sarabhai General (VS) Hospital caters to areas in and around Ahmedabad with an average annual admission secondary to limb or life threatening injuries of about 1200 per year.

Study design: This is a prospective cohort study of injured patients being transported by ambulance to the major trauma centre study sites. The pre-intervention phase will collect data on current practice (observation of current practice and data collection) and will be compared to the intervention phase after the introduction of pre-hospital notification through smartphones.

Study population/recruitment procedure: All injured patients arriving by ambulance and allocated to a red (1st) or yellow (2nd) priority category will be eligible for inclusion. Data will be collected prospectively by trained data collectors positioned in the trauma centres. Pre-hospital data will be abstracted by data collectors from ambulance worksheets at the time of patient arrival. All data will be entered into a trauma registry and patients will be followed up to hospital discharge. A flow chart of the study population is illustrated in Figure 1.

Retrospective inclusion in the registry will be continued for all screened patients presenting to any of the included hospitals with injury (including near-drowning) as the primary diagnosis and with at least one of the following criteria:

1. Admission to hospital
2. Death after triage but before admission
3. Dead on arrival

Exclusion criteria: Patients meeting screening criteria will be subsequently excluded from the registry if they meet any of the following criteria:

1. Dead at scene (i.e. not transported to hospital)
2. Alive at triage but not admitted to hospital (discharged alive without hospital admission)
3. Isolated poisoning
4. Isolated burns
5. Single digit finger or toe amputations (unless of the thumb or great toe), only

Intervention: The pre-hospital notification application (named Suchana) is an android application that will be used by ambulance and emergency clinicians in India to notify emergency departments of selected hospitals of an impending arrival of a patient requiring advanced lifesaving assistance. Pre-hospital clinicians will receive training on use of this application which will be accessible from personal smartphones. The application will use a simple algorithm based on trauma triage principles developed by the Australia India Trauma Systems Collaboration (AITSC).

The Suchana application will be accessed by emergency medical technician via a unique login and device registration. No identifying information is collected by the application with an incident identification number linking the application data to the AITSC Trauma Registry, which is hosted on a secure hospital server in Delhi. The network traffic between the application and the hospital server is Secure Sockets Layer (SSL) encrypted with HTTPS based protocols.

The pre-hospital notification application will be able to collect basic patient identifiers and using an algorithm designed by the AITSC, push derived information to designated receivers. The pre-hospital triage process for injured patients was collaboratively developed using a combination of the current AIIMS trauma flag system (Figure 2), the Field Triage Decision Scheme developed by the American College of Surgeons and guidelines for trauma triage at The Alfred Hospital Emergency & Trauma Centre, Victoria, Australia.[3 7] Data points were determined after taking into account the variation in training among pre-hospital clinicians in the study setting, avoiding criteria that require a high level of clinical judgment. The final algorithm is presented in Table 1 and on the basis of selected criteria, classifies patients to three priorities for trauma resuscitation:

Priority 1 (Red): Serious life threatening injury/illness
Victims with life-threatening injuries or illness (such as head injuries, severe burns, severe bleeding, cardiac arrest, breathing-impaired, internal injuries) are assigned a priority 1 or "Red" Triage tag code (meaning first priority for treatment).
Priority 2 (Yellow): Moderate to serious injury/illness (not immediately life-threatening).
Victims with potentially serious (but not immediately life-threatening) injuries (such as fractures) are assigned a priority 2 or "Yellow" (meaning second priority for treatment) Triage tag code.
Priority 3 (Green): "Walking-wounded" Victims who are not seriously injured
Triaged as "walking wounded", and a priority 3 or "green" classification (meaning delayed treatment).

Demographics: Patient demographics will be collected to define the population and ensure selection of a representative sample. Data collected will include data and time of presentation, age, sex, place of residence.

Exposure variables: Data collected on pre-hospital variables will include vital signs- systolic blood pressure (in mm Hg), pulse rate (in beats/min), respiratory rate (in breaths/min), and consciousness on the alert, voice, pain, responsive (AVPU) scale. Mechanism and place of injury details will also be collected (Table 1). These will be measured by pre-hospital staff after first contact with the patient. In the pre-hospital phase, this will be recorded in paper format as per current practice and extracted by study personnel on arrival to hospital. During the intervention phase, this data will be entered directly into the application. The pre-hospital trauma priority flag (red, yellow or green) will be collected as communicated by hospital staff on arrival to the ED or in the intervention phase, as generated by the intervention or communicated by pre-hospital staff.

Data on demographic and injury characteristics will be collected and include designation of person receiving notification, mechanism and intent of injury, transport type. Data on clinical signs will include in-hospital vital signs- systolic blood pressure, heart rate, respiratory rate and GCS with additional data on GCS components and oxygen saturation. Management data collected will include emergency department disposition times, details on in-hospital operative procedures, in-hospital radiological investigations, neurosurgical consultation, and blood transfusions. Further details on injury severity will be collected using the Abbreviated Injury Severity (AIS) scale codes (2005 Update 2008 (AIS 2008)).[8]

Table 1. Pre-hospital data collection using smartphone application and generation of trauma priority flag

Demographics	Age - Years Sex
Mechanism of injury	RTI - (Road traffic incident) High Speed RTI pedestrian / bicycle RTI motorbike RTI unspecified Fall from height (10 feet/3 metres)[a] Penetrating trauma- Stab / Gunshot[a] Railway incident[a] Blunt Assault Near drowning[a] Other
Serious Injury Identification	Penetrating to head, neck, torso[a] Chest injury including pneumothorax[a] Crush injury including degloving[b] Amputation proximal to wrist and ankle[a] Suspected pelvic injury[b] Open or closed suspected skull fracture[a] Spinal Injury[a] Other
Vital Signs	Systolic Blood Pressure - Record actual value in mmHg - < 90[a] - ≥ 90 Heart Rate - Record actual value – heart rate per minute - ≥ 120[b] - <120 Respiratory Rate - Record actual value – respirations per minute - <12 beats per minute[b] - >24 beats per minute[b] - Normal – 12 – 24 AVPU - Alert - Verbal[a] - Responding to Pain[a] - Unconscious[a]

AUTOMATIC FLAG-GENERATION RULES

[a] Presence of a variable generates a RED flag
[b] Presence of two or more variables generates a RED flag
[b] Presence of one variable only generates a YELLOW flag
Presence of none of the numbered variables generates a GREEN flag

Primary Outcome: Pre-hospital notification will be the primary outcome, defined as a phone call or message to a treating hospital clinician regarding an injured patient en route to hospital. For the purpose of this research project, a patient will satisfy primary outcome criteria if pre-hospital notification with any information has occurred. This variable will be collected and analysed as a binary variable.

Secondary outcomes: A trauma call-out will be recorded as a binary variable- whether one has occurred or not. Date and time of this callout will also be recorded.

The presence of a trauma team leader at the time of patient arrival will be collected as a binary variable. This is the person whose role is to co-ordinate the trauma resuscitation (primary and secondary survey) - this is, generally, a hands-off role undertaken by the most senior clinician in the trauma team. The team leader should be someone not already/always present in the area where trauma bay is located; and have the ability to lead or make decisions regarding treatment (e.g. emergency transfer to operating theatre or not). The leader is expected to be present by the time of patient arrival at the definitive care hospital. The designation of the usual team leader is site specific:
JPN: Senior Resident
GTBH: Senior Resident
VSH: Third year Resident
LTMGH: Third year surgical resident

Readiness of a trauma bay is defined as at least 1 trauma bay that has been allocated and empty (therefore ready to receive a patient) on arrival. Time at which the first chest x-ray commenced will be recorded. The location to which a patient was discharged on completion of hospital management will be recorded and the secondary outcome for in-hospital death collected as a binary variable.

Pre-defined subgroup analyses will be conducted on each centre, severity of injury on presentation, i.e. “red” and “yellow” category and patients who are declared dead on arrival.

Data analysis: Continuous data will be summarised using mean with standard deviation if normally or near-normally distributed or with medians and inter-quartile ranges for skewed data. Ordinal data will be summarised using medians and inter-quartile ranges. Nominal, including binary, data will be presented as counts with proportions within their categories. Statistical significance will be defined as $p<0.05$. A difference between means will be analysed for statistical significance using the Student's t-test while the Wilcoxon Rank Sum test will be used for assessing statistical significance for a difference between medians. The chi-squared test or Fisher's exact test will be used for nominal data according to cell frequencies. All analyses will be performed using Stata v 12.0 (Statacorp, College Station, Texas, USA).

Sample size: The proportion of patients achieving the primary outcome after intervention was targeted to be 0.70 (achieved by consensus among trauma leaders in Australia and India). This was considered to be a clinically significant level compared to anecdotal reports of current practice at extremely low rates of pre-hospital notification.

The minimum acceptable difference from this hypothesized ideal proportion was considered to be 10%, with a one-sided absolute difference of >10% (i.e. less than 0.6) to be considered as failure to achieve the primary outcome. The estimated sample size for a one-sample comparison of proportion with the hypothesized value of 0.70, an alpha of 0.05 and power of 0.90 was 191 after intervention.

Funding: This project is part of the Australia-India Trauma Systems Collaboration (AITSC) that brings together public and private sector clinicians and researchers to improve information, resources and pilot new systems of care. Commencing in 2013, the Australian and Indian Governments invested through their Australia-India Strategic Research Fund Grand Challenge Scheme, to find the best ways of delivering needed care to injured people. The AITSC is funded through the former Grand Challenge Fund. Australia's Department of Industry, Innovation, and Science (DIIS) and the Government of India's Department of Science and Technology (DST) jointly manage the Grand Challenge Fund. It is expected that these projects will lay the foundations for a national trauma system in India, and improved trauma care in much of Australia. They will also provide needed evidence about low-cost trauma system interventions that could be implemented in most countries without the need for major health system redesign.

Ethics and dissemination: Although this study primarily involves service evaluation, ethical approval was obtained to allow collection of patient identifiers. Therefore, full ethical approval has been obtained from the All India Institute of Medical Sciences (AIIMS), New Delhi, India, and site-specific approval has been acquired from the relevant trauma services. The project has been reviewed by the Monash University Human Research Ethics Committee and approval granted; Project number: CF16/1814 – 2016000929. Study results will be disseminated among pre-hospital and hospital clinicians across participating sites. It is expected ongoing evaluation will inform sustainability of the proposal and requirements for refreshers. It is expected that study findings will be presented at scientific congresses and published in peer-reviewed manuscripts.

The protocol is registered at clinicaltrial.gov, ID No: NCT02877342.

DISCUSSION

Currently, injury in India is a leading cause of years of productive life lost and the leading cause of death for those under 35 years old. This national injury burden is growing and the ongoing rise in the trauma burden is mostly in the form of road traffic crashes. India has 1% of the total vehicles in the world yet accounts for 6% of total road accidents globally. It is estimated that there are 400,000 road traffic crashes in India each year, resulting in 100,000 deaths and 1.2 million individuals who are seriously injured. The burden is borne disproportionately by young people with a regional report concluding a total of 6134 life years were lost each year in a population of 108 000 following unintentional injuries.[9]

International establishment of trauma systems incorporating centralised trauma centres has helped address the injury burden by providing prompt, specialist trauma care. In such systems, effective therapy for the severely injured is facilitated by an interdisciplinary and integrated (horizontal) approach to undifferentiated trauma with input from pre-hospital and in-hospital resuscitation teams.[10]

This will be the first study to assess utilisation of a smartphone-based intervention to improve pre-hospital notification. Smartphones currently include all the features of a laptop, including web browsing, Wi-Fi, and third-party application. Currently the most popular smartphones are Google's Android, Apple's IOS mobile operating systems and Nokia-X series. As well as being technologically advanced, India’s adoption of smartphones and tablets has been high and continues to rapidly grow. Doctors in emergency departments have smartphones and ambulance services have access to smartphones and/or tablets in their ambulances. Similar technology has been successfully used to monitor patients with chronic health needs and self-examination.[11] There is currently no standardised system of pre-hospital notification in India for injured patients. The public ambulance system in India is rapidly expanding, adopting computerised systems of GPS tracking and call allocation similar to high-income countries.

Additional data from this project mayidentify potential benefits from new approaches to communication between pre-hospital care providers (ambulance, emergency, and police services) and receiving hospitals, before the patient arrives. As this project will use standardised, locally tailored protocols for notifying and responding to a seriously injured person who is being brought to hospital, there is further scope for validating such protocols for more widespread use.

Previous studies evaluating trauma outcomes in India have been limited with absence of pre-hospital data and inability to evaluate the influence of pre-hospital factors on trauma outcomes.[12] This intervention and the accompanying registry will be among the first to include robust pre-hospital data, collected prospectively, in evaluating trauma outcomes. Trauma registries are integral to trauma system improvement. In developing countries, where the burden of injury is much greater, the known activity of trauma registries is much less.[13]

This project is fully funded and has progressed to development of the smartphone application and training of data collectors. Relevant ethics committee approvals as described above have been obtained. Pre-intervention data collection commenced in May 2016. The intervention will commence in February 2017, with expected completion of the project by May 2017.

CONCLUSIONS

Routine pre-hospital notification of injured patients to the receiving trauma centre is currently not practiced in India. This study will prospectively record the current practice of pre-hospital notification, management across pre-hospital and hospital phases and outcomes of injured patients presenting to four major trauma centres in India. We aim to develop a smartphone application, incorporating essential information for accurate triage of injured patients. The effect of this intervention on pre-hospital notification rates, along with overall trauma processes and outcomes will be evaluated in a prospective observational study. It is expected that successful evaluation will enable widespread adoption of this intervention in India and other countries.

CONTRIBUTORSHIP Statement

The project was planned by RG, MF, MM, AM and AT. Study design was undertaken, in consultation with all authors, by BM, PC, TH, MF, VK and JM. Site-specific processes were arranged and processes unique to each site added to the manuscript by KS, GK, SD and PP. Biostatistician GO reviewed the proposal and provided input to research design and analysis. MS and TW provided expert opinion on pre-hospital systems. All authors reviewed and edited the final manuscript.

Conflicts of Interest

None to declare

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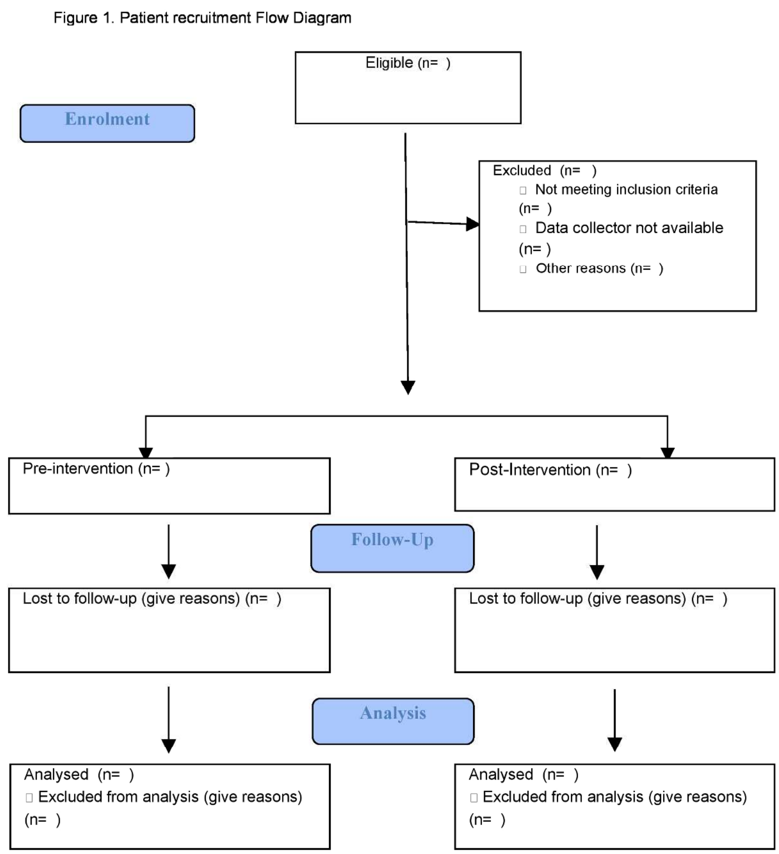

Figure 1. Patient recruitment flow diagram

209x297mm (300 x 300 DPI)

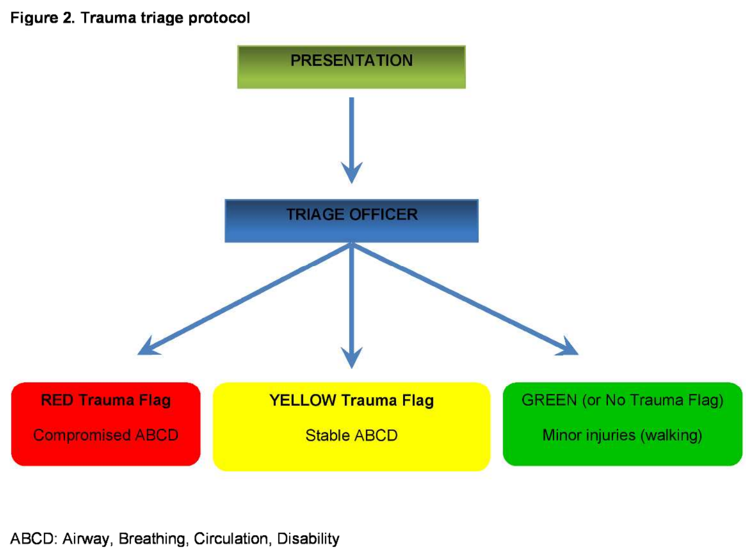

Figure 2. Trauma triage protocol

209x297mm (300 x 300 DPI)

Protocol for a prospective observational study to improve pre-hospital notification of injured patients presenting to trauma centres in India

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Complete List of Authors:	Mitra, Biswadev; Monash University, National Trauma Research Instiutute Mathew, Joseph; The Alfred Hospital, National Trauma Research Institute Gupta, Amit; All India Institute of Medical Sciences, Surgery Cameron, Peter; Monash University, Department of Epidemiology and Preventive Medicine O'Reilly, Gerard; Monash University, National Trauma Research Institute Soni, Kapil; All India Institute of Medical Sciences, Surgery Kaushik, Gaurav; All India Institute of Medical Sciences, Surgery Howard, Teresa; The Alfred Hospital, National Trauma Research Institute Fahey, Madonna; Monash University, National Trauma Research Institute Stephenson, Michael; Ambulance Victoria Kumar, Vineet; Lokmanya Tilak Municipal Medical College and General Hospital, Surgery Vyas, Sharad; BJ Medical College Dharap, Satish; Lokmanya Tilak Municipal Medical College and General Hospital, Surgery Patel, Pankaj; Smt NHL Municipal Medical College, Orthopaedic Surgery Thakor, Advait; Smt NHL Municipal Medical College Sharma, Naveen; All India Institute of Medical Sciences, Surgery Walker, Tony; Ambulance Victoria Misra, Mahesh; All India Institute of Medical Sciences, Surgery Gruen, Russell; Nanyang Technological University Fitzgerald, Mark; The Alfred Hospital, National Trauma Research Institute

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Protocol for a prospective observational study to improve pre-hospital notification of injured patients presenting to trauma centres in India

Biswadev Mitra, MBBS, MHSM, PhD, FACEM

Amit Gupta, MBBS, FSIM, FCLS, FACS

Prof Peter A. Cameron, MBBS, MD, FACEM

Gerard O'Reilly, MBBS, MPH, MBiostat, PhD, AStat, FACEM

Kapil Dev Soni, MBBS, MD

Gaurav Kaushik, MSc, PhD

Teresa Howard, BSc, PhD

Madonna Fahey, BA

Michael Stephenson, ASM, B Hlth Sci, Grad Dip Hlth Sci (MICA), RN

Vineet Kumar, MBBS, DNB(Surgery), FNB(Trauma Care)

Sharad Vyas, BSc, MS, LLb, MJS, PGDHHM, DCh

Satish Dharap, MBBS, MS, DNB

Prof Pankaj Patel, MS (Ortho), FASIF

Advait Thakor, MBBS, MD, DA

Naveen Sharma, MBBS, MS(Surgery)

Tony Walker, ASM, FPA

Prof Mahesh C. Misra, MBBS, MS(Surgery), FACS, FAMS, FRCS

Prof Russell Gruen, MBBS, PhD, FRACS

Prof Mark C. Fitzgerald, MBBS, MD, FACEM

Joseph Mathew, MBBS, FACEM

On behalf of the Australia-India Trauma System Collaboration

Correspondence:

Biswadev Mitra

89 Commercial Road, Melbourne, Victoria 3004

P: +61 39076 2782

F: +61 39076 2699

E: biswadev.mitra@monash.edu

ABSTRACT

Introduction: Pre-hospital notification of injured patients enables prompt and timely care in hospital through adequate preparation of trauma teams, space, equipment and consumables necessary for resuscitation, and may improve outcomes. In India, anecdotal reports suggest that prehospital notification, in those few places where it occurs, is unstructured and not linked to a well-defined hospital response. The aim of this manuscript is to describe, in detail, a study protocol for the evaluation of a formalised approach to prehospital notification.

Methods and Analysis: This is a longitudinal prospective cohort study of injured patients being transported by ambulance to major trauma centres in India. In the pre-intervention phase, prospective data on patients will be collected on pre-hospital assessment, notification, in-hospital assessment, management and outcomes and recorded in a new tailored multi-hospital trauma registry. All injured patients arriving by ambulance and allocated to a red or yellow priority category will be eligible for inclusion. The intervention will be a pre-hospital notification application to be used by ambulance clinicians to notify emergency departments of the impending arrival of a patient. The proportion of eligible patients arriving to hospital after notification will be the primary outcome measure. Secondary outcomes evaluated will be availability of a trauma cubicle, presence of a trauma team on patient arrival, time to first chest x-ray and in-hospital mortality.

Progress: Ethical approval has been obtained from the All India Institute of Medical Sciences, New Delhi and site-specific approval granted by relevant trauma services. Results will be fed back to pre-hospital and hospital clinicians via a series of reports and presentations. These will be used to facilitate discussions about service redesign and implementation. It is expected that evidence for improved outcomes will enable widespread adoption of this intervention among centres in all settings with less established tools for pre-hospital assessment and notification.

Strengths and limitations of this study

Strengths:

- This study attempts to address the burden of trauma in a setting with high incidence of injuries and high mortality rates.
- Most deaths occur pre-hospital and interventions in this setting have the potential to deliver the greatest benefit
- This is the first study on implementation and evaluation of a structured pre-hospital notification system in India

- Association of the intervention to hospital mortality will further define the value of such intervention

Limitations:

- This study includes only patients transported by ambulance to four trauma centres in India, and thus will capture only a small proportion of the population at risk
- Outcomes are limited to in-hospital analysis and further studies will be required to assess longer term functional outcomes of injured patients

BACKGROUND

There is now growing evidence that providing trauma care within a well-organized system saves many lives and prevents long-term disability.[1-3] The basis of a well-organized trauma system is an agreed trauma triage process at each step along the patient journey. The correct level of pre-hospital response is based on specified criteria. This is then followed by transfer to an appropriate facility based on patient, mechanistic, and geographic data. The hospital response on patient arrival is based on this pre-hospital data with additional information about pre-hospital treatment and response to early treatment.

In major trauma resuscitation, management of immediately life-threatening injuries requires rapid identification and management of threats to airway, breathing, circulation and brain function. With sufficient notice, trauma hospitals can usually mobilise a team with relevant expertise, which may involve an anaesthetist, surgeon and emergency physician, specialist nurses and a radiographer, to be present and ready for patient arrival. Pre-hospital notification alone has been found to be independently associated with reduced mortality in trauma centres.[4] Some notification is common in highly developed trauma systems, usually by radio to the triage desk of the receiving hospital, although standards have not been set for the format or content of communicated information.

In India, patients are brought to hospital by various means, e.g. in Delhi 42% of the 9021 seriously injured were transported by Delhi Police, whereas only 2% were transported by ambulance in 2014.[5] Pre-hospital notification is rare but is theoretically possible because ambulance and police usually carry Very High-Frequency (VHF) radio units. Most pre-hospital and hospital staff carry personal mobile phones that may also be used for communication. In addition to expediting specialist care on arrival to hospital, pre-hospital communication also enables information sharing from the trauma centre to the caller (such as “ensure the airway is clear” or “if you can see the bleeding site, apply pressure”), which may be valuable for variably trained non-medical transporters.

The primary aim of this project is to evaluate the effectiveness of a protocolised pre-hospital notification system using existing smartphones to improve the rate of pre-hospital notification of injured patients arriving to major trauma centres. Secondary aims were to assess the effect of this intervention on the availability of an appropriate trauma cubicle on patient arrival, the formation of an appropriate receiving trauma team, time to first radiological imaging and in-hospital mortality.

METHODS

Setting: The study will be conducted in four major trauma centres in India. In India, any teaching hospital serviced by specialty departments of general surgery, orthopaedics and neurosurgery are considered to be major trauma centres. The Jai Prakash Narayan Apex Trauma Center, All India Institute of Medical Sciences (AIIMS), New Delhi admits approximately 4000 severely injured (ISS>12) patients per year. Guru Tegh Bahadur (GTB) Hospital is a 1,500-bed hospital situated in the National Capital Region of Delhi, India, with a trauma census of approx. 1500 patients per year with limb or life threatening injuries. The Lokmanya Tilak Municipal General (LTMG) Hospital is a Level I trauma centre, which caters to the megapolis of Mumbai and receives about 2500 patients with limb or life threatening injuries per year. The Sheth Vadilal Sarabhai General (VS) Hospital caters to areas in and around Ahmedabad with an average annual admission secondary to limb or life threatening injuries of about 1200 per year.

Study design: This is a prospective cohort study of injured patients being transported by ambulance to the major trauma centre study sites. The pre-intervention phase will collect data on current practice (observation of current practice and data collection) and will be compared to the intervention phase after the introduction of pre-hospital notification through smartphones.

Study population/recruitment procedure: All injured patients arriving by ambulance and allocated to a red (1st) or yellow (2nd) priority category will be eligible for inclusion. Data will be collected prospectively by trained data collectors positioned in the trauma centres. Pre-hospital data will be abstracted by data collectors from ambulance worksheets at the time of patient arrival. All data will be entered into a trauma registry and patients will be followed up to hospital discharge. A flow chart of the study population is illustrated in Figure 1.

Retrospective inclusion in the registry will be continued for all screened patients presenting to any of the included hospitals with injury (including near-drowning) as the primary diagnosis and with at least one of the following criteria:

1. Admission to hospital
2. Death after triage but before admission
3. Dead on arrival

Exclusion criteria: Patients meeting screening criteria will be subsequently excluded from the registry if they meet any of the following criteria:

1. Dead at scene (i.e. not transported to hospital)
2. Alive at triage but not admitted to hospital (discharged alive without hospital admission)
3. Isolated poisoning
4. Isolated burns
5. Single digit finger or toe amputations (unless of the thumb or great toe), only

Data on injured patients arriving by other means, e.g. private car or police will be included in the registry and numbers and outcomes reported, but not analysed as an outcome of the intervention, as the intervention would not be available to such patients as part of this study.

Intervention: The pre-hospital notification application (named Suchana) is an android application that will be used by ambulance and emergency clinicians in India to notify emergency departments of selected hospitals of an impending arrival of a patient requiring advanced lifesaving assistance. Pre-hospital clinicians will receive training on use of this application which will be accessible from personal smartphones. The application will use a simple algorithm based on trauma triage principles developed by the Australia India Trauma Systems Collaboration (AITSC).

The Suchana application will be accessed by emergency medical technician via a unique login and device registration. No identifying information is collected by the application with an incident identification number linking the application data to the AITSC Trauma Registry, which is hosted on a secure hospital server in Delhi. The network traffic between the application and the hospital server is Secure Sockets Layer (SSL) encrypted with HTTPS based protocols.

The pre-hospital notification application will be able to collect basic patient identifiers and using an algorithm designed by the AITSC, push derived information to designated receivers. The pre-hospital triage process for injured patients was collaboratively developed using a combination of the current AIIMS trauma flag system (Figure 2), the Field Triage

Decision Scheme developed by the American College of Surgeons and guidelines for trauma triage at The Alfred Hospital Emergency & Trauma Centre, Victoria, Australia.[3 6] Data points were determined after taking into account the variation in training among pre-hospital clinicians in the study setting, avoiding criteria that require a high level of clinical judgment. The final algorithm is presented in Table 1 and on the basis of selected criteria, classifies patients to three priorities for trauma resuscitation:

Priority 1 (Red): Serious life threatening injury/illness
Victims with life-threatening injuries or illness (such as head injuries, severe burns, severe bleeding, cardiac arrest, breathing-impaired, internal injuries) are assigned a priority 1 or "Red" Triage tag code (meaning first priority for treatment).
Priority 2 (Yellow): Moderate to serious injury/illness (not immediately life-threatening).
Victims with potentially serious (but not immediately life-threatening) injuries (such as fractures) are assigned a priority 2 or "Yellow" (meaning second priority for treatment) Triage tag code.
Priority 3 (Green): "Walking-wounded" Victims who are not seriously injured
Triaged as "walking wounded", and a priority 3 or "green" classification (meaning delayed treatment).

Demographics: Patient demographics will be collected to define the population and ensure selection of a representative sample. Data collected will include data and time of presentation, age, sex, place of residence.

Exposure variables: Data collected on pre-hospital variables will include vital signs- systolic blood pressure (in mm Hg), pulse rate (in beats/min), respiratory rate (in breaths/min), and consciousness on the alert, voice, pain, responsive (AVPU) scale. Mechanism and place of injury details will also be collected (Table 1). These will be measured by pre-hospital staff after first contact with the patient. In the pre-hospital phase, this will be recorded in paper format as per current practice and extracted by study personnel on arrival to hospital. During the intervention phase, this data will be entered directly into the application. The pre-hospital trauma priority flag (red, yellow or green) will be collected as communicated by hospital staff on arrival to the ED or in the intervention phase, as generated by the intervention or communicated by pre-hospital staff.

Data on demographic and injury characteristics will be collected and include designation of person receiving notification, mechanism and intent of injury, transport type. International

Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD10) External Cause Codes will be collected for Activity, Location and Intent. For Mechanism, ICD10 codes will be aggregated and condensed to improve feasibility, completeness and accuracy. Data on clinical signs will include in-hospital vital signs- systolic blood pressure, heart rate, respiratory rate and GCS with additional data on GCS components and oxygen saturation. Management data collected will include emergency department disposition times, details on in-hospital operative procedures, in-hospital radiological investigations, neurosurgical consultation, and blood transfusions. Further details on injury severity will be collected using the Abbreviated Injury Severity (AIS) scale codes (2005 Update 2008 (AIS 2008)).[7]

Table 1. Pre-hospital data collection using smartphone application and generation of trauma priority flag

Demographics	Age - Years Sex
Mechanism of injury	RTI - (Road traffic incident) High Speed RTI pedestrian / bicycle RTI motorbike RTI unspecified Fall from height (10 feet/3 metres)[a] Penetrating trauma- Stab / Gunshot[a] Railway incident[a] Blunt Assault Near drowning[a] Other
Serious Injury Identification	Penetrating to head, neck, torso[a] Chest injury including pneumothorax[a] Crush injury including degloving[b] Amputation proximal to wrist and ankle[a] Suspected pelvic injury[b] Open or closed suspected skull fracture[a] Spinal Injury[a] Other
Vital Signs	Systolic Blood Pressure - Record actual value in mmHg - < 90[a] - ≥ 90 Heart Rate - Record actual value – heart rate per minute - ≥ 120[b] - <120 Respiratory Rate - Record actual value – respirations per minute - <12 beats per minute[b]

	- >24 beats per minute[b] - Normal – 12 – 24 AVPU - Alert - Verbal[a] - Responding to Pain[a] - Unconscious[a]

AUTOMATIC FLAG-GENERATION RULES

[a] Presence of a variable generates a RED flag
[b] Presence of two or more variables generates a RED flag
[b] Presence of one variable only generates a YELLOW flag
Presence of none of the numbered variables generates a GREEN flag

Primary Outcome: Pre-hospital notification will be the primary outcome, defined as a phone call or message to a treating hospital clinician regarding an injured patient en route to hospital. For the purpose of this research project, a patient will satisfy primary outcome criteria if pre-hospital notification with any information has occurred. This variable will be collected and analysed as a binary variable.

Secondary outcomes: A trauma call-out will be recorded as a binary variable- whether one has occurred or not. Date and time of this callout will also be recorded.

The presence of a trauma team leader at the time of patient arrival will be collected as a binary variable. This is the person whose role is to co-ordinate the trauma resuscitation (primary and secondary survey) - this is, generally, a hands-off role undertaken by the most senior clinician in the trauma team. The team leader should be someone not already/always present in the area where trauma bay is located; and have the ability to lead or make decisions regarding treatment (e.g. emergency transfer to operating theatre or not). The leader is expected to be present by the time of patient arrival at the definitive care hospital. The designation of the usual team leader is site specific:

JPN: Senior Resident

GTBH: Senior Resident

VSH: Third year Resident

LTMGH: Third year surgical resident

Readiness of a trauma bay is defined as at least 1 trauma bay that has been allocated and empty (therefore ready to receive a patient) on arrival. Time at which the first chest x-ray commenced will be recorded. The location to which a patient was discharged on completion of hospital management will be recorded and the secondary outcome for in-hospital death collected as a binary variable.

Pre-defined subgroup analyses will be conducted on each centre, severity of injury on presentation, i.e. “red” and “yellow” category and patients who are declared dead on arrival.

Data analysis: Continuous data will be summarised using mean with standard deviation if normally or near-normally distributed or with medians and inter-quartile ranges for skewed data. Ordinal data will be summarised using medians and inter-quartile ranges. Nominal, including binary, data will be presented as counts with proportions within their categories. Statistical significance will be defined as $p<0.05$. A difference between means will be analysed for statistical significance using the Student’s t-test while the Wilcoxon Rank Sum test will be used for assessing statistical significance for a difference between medians. The chi-squared test or Fisher’s exact test will be used for nominal data according to cell frequencies. All analyses will be performed using Stata v 12.0 (Statacorp, College Station, Texas, USA).

Sample size: The proportion of patients achieving the primary outcome after intervention was targeted to be 0.70 (achieved by consensus among trauma leaders in Australia and India). This was considered to be a clinically significant level compared to anecdotal reports of current practice at extremely low rates of pre-hospital notification.

The minimum acceptable difference from this hypothesized ideal proportion was considered to be 10%, with a one-sided absolute difference of >10% (i.e. less than 0.6) to be considered as failure to achieve the primary outcome. The estimated sample size for a one-sample comparison of proportion with the hypothesized value of 0.70, an alpha of 0.05 and power of 0.90 was 191 after intervention.

Funding: This project is part of the Australia-India Trauma Systems Collaboration (AITSC) that brings together public and private sector clinicians and researchers to improve information, resources and pilot new systems of care. Commencing in 2013, the Australian and Indian Governments invested through their Australia-India Strategic Research Fund Grand Challenge Scheme, to find the best ways of delivering needed care to injured people. The AITSC is funded through the former Grand Challenge Fund. Australia’s Department of Industry, Innovation, and Science (DIIS) and the Government of India’s Department of Science and Technology (DST) jointly manage the Grand Challenge Fund. It is expected

that these projects will lay the foundations for a national trauma system in India, and improved trauma care in much of Australia. They will also provide needed evidence about low-cost trauma system interventions that could be implemented in most countries without the need for major health system redesign.

Ethics and dissemination: Although this study primarily involves service evaluation, ethical approval was obtained to allow collection of patient identifiers. Therefore, full ethical approval has been obtained from the All India Institute of Medical Sciences (AIIMS), New Delhi, India, and site-specific approval has been acquired from the relevant trauma services. The project has been reviewed by the Monash University Human Research Ethics Committee and approval granted; Project number: CF16/1814 – 2016000929. Study results will be disseminated among pre-hospital and hospital clinicians across participating sites. It is expected ongoing evaluation will inform sustainability of the proposal and requirements for refreshers. It is expected that study findings will be presented at scientific congresses and published in peer-reviewed manuscripts.

The protocol is registered at clinicaltrial.gov, ID No: NCT02877342.

DISCUSSION

Currently, injury in India is a leading cause of years of productive life lost and the leading cause of death for those under 35 years old. This national injury burden is growing and the ongoing rise in the trauma burden is mostly in the form of road traffic crashes. India has 1% of the total vehicles in the world yet accounts for 6% of total road accidents globally. It is estimated that there are 400,000 road traffic crashes in India each year, resulting in 100,000 deaths and 1.2 million individuals who are seriously injured. The burden is borne disproportionately by young people with a regional report concluding a total of 6134 life years were lost each year in a population of 108 000 following unintentional injuries.[8]

International establishment of trauma systems incorporating centralised trauma centres has helped address the injury burden by providing prompt, specialist trauma care. In such systems, effective therapy for the severely injured is facilitated by an interdisciplinary and integrated (horizontal) approach to undifferentiated trauma with input from pre-hospital and in-hospital resuscitation teams.[9]

This will be the first study to assess utilisation of a smartphone-based intervention to improve pre-hospital notification. Smartphones currently include all the features of a laptop, including web browsing, Wi-Fi, and third-party application. Currently the most popular smartphones are Google's Android, Apple's IOS mobile operating systems and Nokia-X series. As well as being technologically advanced, India's adoption of smartphones and tablets has been high and continues to rapidly grow. Doctors in emergency departments have smartphones and ambulance services have access to smartphones and/or tablets in their ambulances. Similar technology has been successfully used to monitor patients with chronic health needs and self-examination.[10] There is currently no standardised system of pre-hospital notification in India for injured patients. The public ambulance system in India is rapidly expanding, adopting computerised systems of GPS tracking and call allocation similar to high-income countries.

Pre-hospital services are rapidly expanding across India with over 20 states with some form of Government or Private-Public Partnership pre-hospital/emergency service. India is rapidly moving toward a Western model of pre-hospital service with the aim that all major trauma patients will arrive by ambulance staffed by personnel trained in basic or advanced life support. Our project is directed toward the ambulance services, while other groups such as the SaveLIFE Foundation, an independent, non-profit, non-governmental organization focused on improving road safety and emergency medical care across India, who have introduced a training program for police as first responders. Other groups that have introduced similar programs in India are the Society of Indian Automotive Manufacturers and the International Road Federation in Geneva.

Additional data from this project may identify potential benefits from new approaches to communication between pre-hospital care providers (ambulance, emergency, and police services) and receiving hospitals, before the patient arrives. As this project will use standardised, locally tailored protocols for notifying and responding to a seriously injured person who is being brought to hospital, there is further scope for validating such protocols for more widespread use. The current scope of the project and funding precludes training and evaluation of non-ambulance care providers and expected success of this project will likely provide the impetus to introduce pre-hospital notification more widely across the country.

Previous studies evaluating trauma outcomes in India have been limited with absence of pre-hospital data and inability to evaluate the influence of pre-hospital factors on trauma outcomes.[11] This intervention and the accompanying registry will be among the first to include robust pre-hospital data, collected prospectively, in evaluating trauma outcomes. Trauma registries are integral to trauma system improvement. In developing countries, where the burden of injury is much greater, the known activity of trauma registries is much less.[12]

This project is fully funded and has progressed to development of the smartphone application and training of data collectors. Relevant ethics committee approvals as described above have been obtained. Pre-intervention data collection commenced in May 2016. The intervention will commence in February 2017, with expected completion of the project by May 2017.

CONCLUSIONS

Routine pre-hospital notification of injured patients to the receiving trauma centre is currently not practiced in India. This study will prospectively record the current practice of pre-hospital notification, management across pre-hospital and hospital phases and outcomes of injured patients presenting to four major trauma centres in India. We aim to develop a smartphone application, incorporating essential information for accurate triage of injured patients. The effect of this intervention on pre-hospital notification rates, along with overall trauma processes and outcomes will be evaluated in a prospective observational study. It is expected that successful evaluation will enable widespread adoption of this intervention in India and other countries.

CONTRIBUTORSHIP Statement

The project was planned by RG, MF, MM, AM and AT. Study design was undertaken, in consultation with all authors, by BM, PC, TH, MF, VK and JM. Site-specific processes were arranged and processes unique to each site added to the manuscript by KS, GK, SD and PP. Biostatistician GO reviewed the proposal and provided input to research design and analysis. MS and TW provided expert opinion on pre-hospital systems. All authors reviewed and edited the final manuscript.

Conflicts of Interest

None to declare

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Figure Legends

Figure 1. Patient recruitment flow diagram

Figure 2. Trauma triage protocol

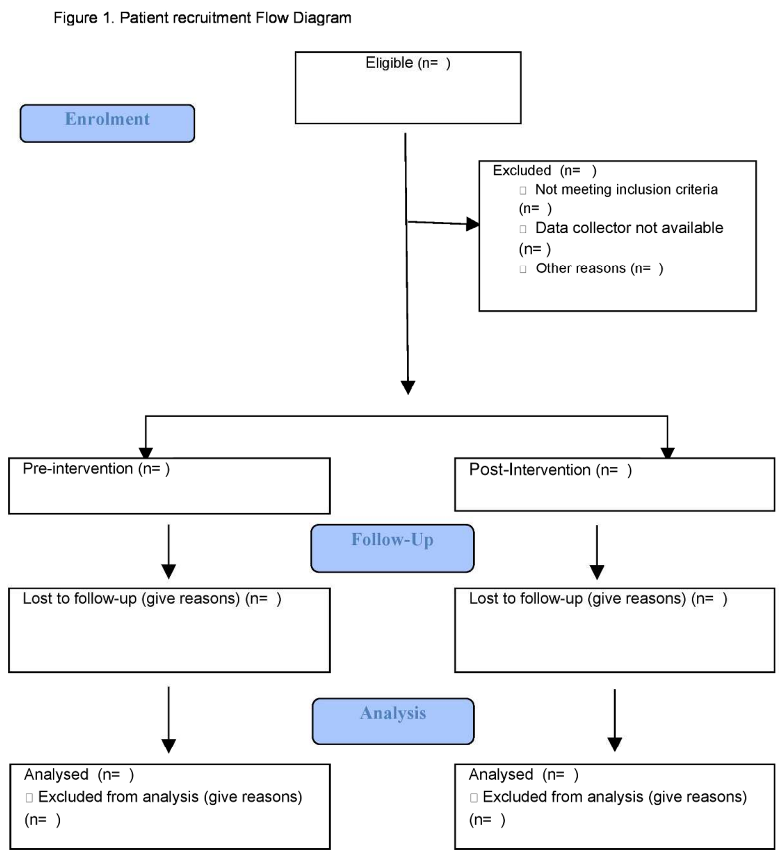
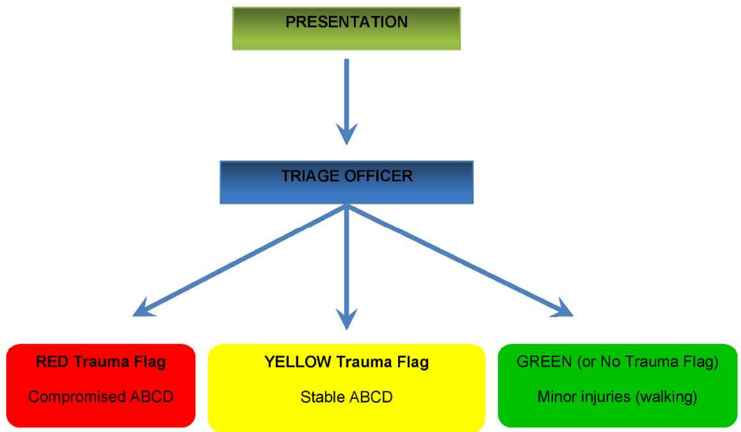


Figure 1. Patient recruitment flow diagram

209x297mm (300 x 300 DPI)

Figure 2. Trauma triage protocol



ABCD: Airway, Breathing, Circulation, Disability

Figure 2. Trauma triage protocol

209x297mm (300 x 300 DPI)